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DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

MD838n

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 4, 1999

Gladys George
President / CEO
Lenox Hill Hospital
100 East 77th Street
New York, NY 10021

Ref: NYK 1999-57

Dear Ms. George:

During our June 9 through June 30, 1999 inspection of the Lenox Hill Hospital blood bank, located at 100 East 77th Street, New York, New York, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetics Act and Title 21, Code of Federal Regulations, (CFR), Parts 600 through 680.

At the conclusion of the inspection, the investigator presented the enclosed Inspectional Observations (Form FDA-483) to Dr. Randy L. Levine, Medical Director of the blood bank, and discussed her findings with him. The following violations were noted:

1. Failure to follow the blood bank's Standard Operating Procedures, (SOP), [21 CFR 606.100], as follows:

   a. A blood bank investigation summary report, dated November 24, 1998 relating to a post transfusion HIV infection, is incomplete, in that, it does not describe the disposition of components or reports of infection from other blood components associated with the affected units, as required by the blood bank's SOP.

   b. Thirteen out of thirty-two Transfusion Reaction Reports were not reviewed by a supervisor, for the time period of January 1998 to June 1999, as required by the blood bank's SOP.

   c. Platelet quality control testing was not done on four units each month, for January 1998, February 1998 and March 1998, as required by the blood bank's SOP.

2. Failure to adequately assess the suitability of donors [21 CFR 640.3] as follows:

   a. Donor registration forms were incomplete and no justification was provided for the acceptance of those donors. For example: high risk activities, bleed times, amount of blood drawn, pulse, were not indicated on the donor registration forms. These include, but are not limited to donor #s: 4953056, 8739948, 4767460, 4551091, 4953045, 4767218.

   b. Donor registration forms indicated the ingestion of aspirin or aspirin-containing medication within 3 days of donation. These donors were not deferred from donation and the donor responses were not referred to the blood bank director for evaluation. Some examples include donor #s: 8739930, 8933737, 8933674, 6446168, 6446696, 6446069, 6446694.

   c. Donor registration forms indicated that the donors traveled outside of the United States, including to malarial risk countries. The historian failed to clarify the specific locations that the donors traveled to. Some examples include donor #s: 8739814, 8391465, 8933604, 8739769, 8391454.

   d. Donor registration form for unit # 8739153 indicated the use of prescription medication by the donor. The historian failed to clarify the name of the prescription medication that the donor used.

3a. Failure to have a written procedure in place for the deferral of unsuitable donors. [21 CFR 606.100]

3b. Failure to place donors of units #s 8933767 and 6422220, into the in-house deferral system to defer the donors from future donations. The units tested repeatedly reactive for HBcAb. [21CFR 606.160]

4. Failure to perform scheduled calibration and/or maintenance on equipment used in the collection and processing of blood and blood components [21 CFR 606.60], as follows:

   a. Daily temperature checks were not performed on the [redacted] refrigerator for January 1 through December 31, 1998, January 1-21,23, and 24, 1999, February 1-11 and 13-21, 1999, March 27-31, 1999, April 1-4, and 18-25, 1999, May 1-31, 1999, and June 1-22, 1999, as required by the blood bank's SOP.

   b. Daily quality control checks were not performed on the [redacted], for January 30, 1998, May 8, 1998, August 7, 1998 and December 1, 1998, as required by the blood bank's SOP.

The above identified violations are not intended to be an all-inclusive list of deficiencies at the blood bank. It is your responsibility as the President and CEO to assure that the blood bank is in compliance with all requirements of the federal regulations.

We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice. Such action may include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Attention: Fabio L. Mattiasich, Compliance Officer. If you have any questions regarding the content of this letter, Mr. Mattiasich can be reached at (718) 340-7000, ext. 5292.

Sincerely,

Brenda J. Holman
District Director

Enclosure: Form FDA-483

cc: Jeanne V. Linden, M.D., M.P.H.
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